REMARKS

1. In response to the Office Action mailed January 23, 2008, Applicant respectfully requests reconsideration. Claims 21-30 were last presented for examination. In the outstanding Office Action, claims 21-25 were rejected. By the foregoing Amendments, claim 21 has been amended. No claims have been added or cancelled. Claims 21-25 are drawn to the elected invention, and claims 25-30 are directed to non-elected invention and may be cancelled upon the allowance of the claims directed to the elected invention. No new matter has been added. Thus, upon entry of this paper, claims 21-30 will be pending in this application. Of these ten (10) claims, two (2) claims (claims 21 and 26) are independent.

2. Support for the amendments to independent claim 21 can be found in the originally filed specification text, claims and drawings. Specifically, support for the amendment "wherein said outer implant diameter is different from said inner implant diameter" can be found in the originally filed specification text at page 2, lines 35-38 and FIG. 2, in addition to other portions of the originally filed application text, drawings and claims. Also, support for the amendment "said GSS configured to be released from said implant surface and further configured to interact" can be found in the originally filed specification on page 8, lines 23 and 31 in addition to FIGS. 3 and 4 and other portions of the originally filed application text, drawings and claims. Furthermore, support for the amendment "whereby a closed space is defined" can be found in can be found in the originally filed specification on page 8, lines 6-15 in addition to FIGS. 2 and 3 and other portions of the originally filed application text, drawings and claims. Finally, support for the amendment "said jaw bone hole is configured to receive bodily fluids" can be found in can be found in the originally filed specification on page 8, lines 25-31 in addition to FIGS. 2-4 and other portions of the originally filed application text, drawings and claims.

3. Based upon the above Amendment and following Remarks, Applicant respectfully requests that all outstanding objections and rejections be reconsidered, and that they be withdrawn.

Double Patenting

4. The Office Action provisionally rejected claims 1-6 and 10-14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 10-17 of copending Application No. 10/520,759. The Office Action alleges that although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art as to the functional limitations of the jaw bone hole and osteoinductive material. Applicant respectfully disagrees for the following reasons.

5. Claim 21, as presently amended, recites:

> An implant for fitting into a jaw bone hole having adjacent soft tissue and inner and outer hole parts with respective inner and outer hole diameters, comprising:
> an inner implant part having an inner implant diameter;
> an outer implant part having an outer implant diameter; and
> at least one growth stimulating substance (GSS) disposed on a surface of said implant configured to interact with at least bodily fluid to form new bone,
> wherein said implant is configured to be covered by the soft tissue,
> wherein said inner implant diameter is configured to be greater than the inner hole diameter, whereby said implant is configured to be anchored to the jaw bone upon fitting said inner implant part into the inner hole part,
> wherein said outer implant diameter is configured to be lesser than the outer hole diameter, ***whereby a closed space is defined by*** at least the jaw bone surface of the outer hole part, said outer implant part ***and the soft tissue***,
> and further wherein said hole configured to receive bodily fluids via the jaw bone and GSS from said implant.
> (*See*, independent claim 21, above; emphasis added.)

Meanwhile, claim 18 of reference Application No. 10/520,759 is directed to:

> An implant for implantation into a hole of a recipient's bone comprising:
> at least one outer surface having a first cross-section diameter configured to be at least approximately equal to the cross-section diameter of the bone hole;
> at least one inner surface having a second cross-section diameter configured to be smaller than both the cross-section diameter of the hole and said first cross-section diameter, wherein ***a space is defined between said outer surface, said inner surface and the recipient's bone***; and
> at least one growth stimulating substance (GSS) retained on said implant.
> (*See*, Application No. 10/520,759, independent claim 18; emphasis added.)

6. Claim 21 of the instant application and claim 18 of the reference application clearly are directed to two distinct structures for defining a space. In the instant application, the claim recites defining a space with soft tissue that is "configured to cover said outer implant part", while the reference application uses two ***implant surfaces***, namely the outer and inner surfaces of the implant, and the bone surface of the hole in the recipient. That is, in an embodiment of the invention disclosed in the reference application, the space that is created does not use any "soft tissue" to define the space described. Unlike the reference application, the invention of the present application is closing the jaw bone hole with the implant fitted therein by means of the "soft tissue... configured to cover said outer implant part." Therefore, Applicant submits that the features of the instant application would not have been obvious to one of ordinary skill in the art as to the functional limitations of the jaw bone hole and osteoinductive material based on the reference application. Accordingly, Applicant respectfully requests that the rejection be reconsidered and that it be withdrawn.

Claim Rejections under § 112

7. Claims 21-25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Office Action asserts that the recitation of "said hole" in claim 21 lacks sufficient antecedent basis. (*See*, Office Action, pg. 3.) Independent claim 21 has been amended to accommodate this rejection.

Claim Rejections under §102 – Gayer

8. Claims 21-25 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,214,049 to Gayer *et al.* (hereinafter, "Gayer"). Gayer fails to anticipate claims 21-25 for at least the following reasons.

9. Gayer is directed to fibrillar wires formed on prosthetic implant devices to enhance "osteointegration and physiologic load distribution of a implant device resulting in prosthetic success when placed in the human body." (*See*, Gayer, Abstract.) As described and shown in FIG. 3 of Gayer, a fibrillar mesh (or titanium-wool mesh) is formed around and attached to implant core 304. The fibrillar mesh is said to be "coated with HA and encased in a carrier

polymer containing osteoinductive and osteoconductive factors." (*See*, Gayer, col. 7, ll. 1-10.) Gayer states that "the fibrillar wool acts to provide sufficient surface area for bone attachment and to strengthen the surrounding bone matrix." (*See*, Gayer, col. 7, ll. 27-28.)

10. Gayer describes new or nascent bone as attaching to and being supported by the fibrillar wire formation, which is in turn attached to the implant 300 via connection "points 306". (*See*, Gayer, col. 7, ll. 39-42.) Specifically, Gayer states:

> An important aspect of the present invention is that new bone growth is induced to integrate with the structure formed by the system of fibrillar wires. The fibrillar wires function as reinforcing rods to provide multidirectional strength to the nascent bone and also distributes over a large internal surface area the physical forces placed upon the implant by body movement. The result is a more structurally secure prosthetic implant device that can withstand greater biomechanical forces. This integral characteristic of the wool mesh makes the present invention ideally suited for improving the strength and fixation of prosthetic devices.
>
> (*See*, Gayer, col. 8, ll. 54-64.)

11. Furthermore, FIG. 10 and 11 of Gayer describes a "section of bone 1000 having an opening or cavity 1002" in which "fibrillar wires or mesh 1102 may be shaped to conform to the size of the bone cavity 1002." (*See*, Gayer, col. 12, ll. 47-60.) As shown in various figures of Gayer, an implant having a uniform diameter is shown as being positioned within cavity 1002. (*See*, Gayer, FIGS. 1,3,4-11.)

12. Applicant's independent claim 21 recites, in part, "An implant [having] inner and outer hole parts with respective inner and outer hole diameters, comprising: an inner implant part having an inner implant diameter; an outer implant part having an outer implant diameter, ***wherein said outer implant diameter is different from said inner implant diameter***... wherein said ***inner implant diameter*** is configured to be ***greater than the inner hole diameter***, whereby said ***implant*** is configured to be ***anchored to the jaw bone upon fitting said inner implant part into the inner hole part.***" (*See*, Applicant's independent claim 21, above; emphasis added.) As claimed, Applicant's implant has an inner part which has a diameter that is greater than the diameter of the inner hole part such that the implant is anchored when the larger object (inner implant part) is fitted inside the smaller hole (inner hole part). This is unlike Gayer, which only describes retaining or otherwise anchoring the implant via multiple connection points which are

connected to a wire mesh which becomes integrated with nascent bone formation. Therefore, Gayer fails to teach or suggest Applicant's invention as claimed.

Claim Rejections under §102 – Driskell

13. Claims 21, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,738,623 to Driskell (hereinafter, "Driskell"). Driskell also fails to anticipate claims 21, 24 and 25 for at least the following reasons.

14. Driskell suggests an implant having a "narrowed shoulder around which bone growth stimulating material is packed." (*See*, Driskell, Abstract.) Driskell describes "particles 86 of natural or synthetic bone growth stimulating grafting material... packed within the bone below the crest and around the shoulder 26." (*See*, Driskell, col. 4, ll. 63-67.) FIG. 5 of Driskell shows the growth stimulating material 86 packed around shoulder 26.

15. Driskell does not teach or suggest Applicant's claimed invention, as amended, as Driskell fails to teach or suggest "at least one growth stimulating substance ***(GSS) disposed on a surface of said implant, said GSS configured to be released from said implant surface*** and further configured to interact with at least bodily fluid to form new bone." (*See*, Applicant's independent claim 21, as amended; emphasis added.) As one of ordinary skill in the art would appreciate, the growth stimulating material in Driskell is separate from the implant, as is clear by the fact that it is described as being "packed" in the area around the narrowed shoulder. Unlike Driskell, Applicant's claimed invention has the GSS disposed on the surface of the implant such that it is "released" and interacts with the bodily fluid to form new bone. Therefore, Driskell does not teach or suggest Applicant's invention as claimed.

Dependent claims

16. The dependent claims incorporate all the subject matter of their respective independent claims and add additional subject matter which makes them independently patentable over the art of record. Accordingly, Applicant respectfully asserts that the dependent claims are also allowable over the art of record.

Conclusion

17. In view of the foregoing, this application should be in condition for allowance. A notice to this effect is respectfully requested.

18. Applicant reserve the right to pursue any cancelled claims or other subject matter disclosed in this application in a continuation or divisional application. Any cancellations and amendments of above claims, therefore, are not to be construed as an admission regarding the patentability of any claims and Applicant reserves the right to purse such claims in a continuation or divisional application.

19. In the event that the Examiner believes that an interview would serve to advance the prosecution of this application, the undersigned is available at the number noted below.

20. Please charge fees for a two-month extension along with any other necessary fee due with this response to our Deposit Account No. 22-0185, under Order No. 21547-00302-US1 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: April 23, 2008

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